



**OREGON
HEALTH SCIENCES UNIVERSITY**

3181 S.W. Sam Jackson Park Road Portland, OR 97201-3098
Mail Code L340, (503) 494-4498, Fax (503) 494-4982

School of Medicine
Department of Diagnostic Radiology

503-494-1214, FAX 503-494-4982, e-mail: brownp@ohsu.edu

1703 '00 DEC 21 P1 57

December 13, 2000

Docket No. 00D-1497
Dockets management Branch
Division of Management Systems and Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

The attached comments refer to MQSA Guidance Document #4.

1. Under Quality Control (QC) – General, in the table on p.11, it says that a Survey of a mammographic unit includes "All tests in 900.12(e)(2), (e)(5) ..." I note in particular that 900.12(e)(5)(viii) is Uniformity of screen speed, so this Guidance Document#4 states that uniformity of screen speed is part of mammographic unit test. This is contrary to previous written communications I have had with FDA/CDRH, which stated that Uniformity of screen speed was NOT part of a mammographic unit test; Uniformity of screen speed is only included in a facility survey, not a unit survey. The table on p.11 should be changed to exclude Uniformity of screen speed from a requirement of a Survey of a mammographic unit.
2. I found it pretty confusing, on p. 8 it says that in addition to contact configuration, all configurations (i.e. grid, nongrid, ...) must be tested by the physicist for AEC OD uniformity 2-6 cm. Whereas on p. 16 it conflicts by saying that the physicist does NOT have to test configurations other than contact. Which is it, is testing all configurations for AEC OD 2-6 cm required, or not? I think I figured it out, that p. 8 refers to physicist equipment evaluations after install or repair (must test AEC all configurations), whereas p. 16 refers to the annual physicist facility survey (must test AEC only in contact). It surely is confusing reading. If my interpretation is correct, then I would suggest that the Guidance be modified, so p. 8 specifies that all configurations need NOT be tested during annual physicist survey, and p. 16 should include reference to p. 8, wherein equipment evaluations following install or repair DO require all configurations be tested. Professionally speaking, it is not clear to me that leaving the test for AEC in all configurations out of the annual physicist survey (as on p. 16) will improve the quality of mammography.

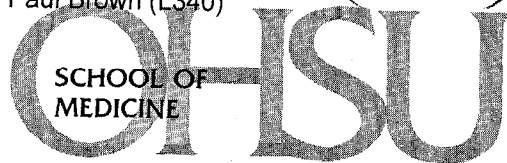
Sincerely,

Paul H. Brown, Ph.D.
Medical Physicist,
Assoc. Prof. Diagnostic Radiology

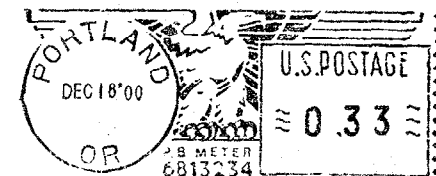
00D-1497

C12

P. Brown (L340)
Paul Brown (L340)



OREGON HEALTH SCIENCES UNIVERSITY
DEPARTMENT OF DIAGNOSTIC RADIOLOGY
3181 SW SAM JACKSON PARK ROAD, MAIL CODE L340
PORTLAND, OREGON 97201-3098



Docket No. 00D-1497
Dockets management Branch
Division of Management Systems and Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061 (HFA-305)
Rockville, MD 20852

20857-0001

